This part of the legislation would provide the money necessary to help a number of States, including my own, avert a funding shortfall in their State Children's Health Insurance Program.

Specifically, the bill will redirect existing unspent SCHIP funds from fiscal years 2004 and 2005 to help States that will not have sufficient funds to maintain their existing programs. States forfeiting unspent funding will be held harmless by capping the amount of funds that will be donated to $20 million. Thanks to this compromise, we can prevent many States from having to limit eligibility, increase cost-sharing requirements or restrict benefits. Keeping these programs intact is critically important for the health and well-being of our Nation's children.

Since its inception, SCHIP has been an integral part of reducing the number of uninsured children. But last year, for the first time since 1998, the number of uninsured children in the country actually increased, and even more children will go without coverage if Congress does not act tonight to avoid the funding shortfall currently projected for next year.

Again, I would like thank my colleagues Mr. DINGELL and Mr. BARTON, as well as their staffs, who helped work out this compromise, as well as our Senate counterparts. Thanks to our efforts, we will help preserve access to health care coverage for millions of low income children, as well as their families.

Finally, Mr. Speaker, while we have temporarily prevented a cut to the SCHIP program tonight, we must not forget that there are still approximately 8 million American children who currently have no health insurance, many of which are eligible to participate in SCHIP. Reauthorization of the SCHIP program must be addressed early next year and we must work together to help expand coverage and increase participation. Failure to do so will undoubtedly jeopardize the health of those most vulnerable in our Nation, our children.

I would like to thank everyone again.

Mr. Speaker, I yield back the balance of my time.

Mr. BARTON of Texas. Mr. Speaker, I urge that we pass this bill unanimously, and I yield back the balance of my time.

The SPEAKER pro tempore (Mr. LAHOOD). The question is on the motion offered by the gentleman from Texas (Mr. BARTON) that the House suspend the rules and concur in the Senate amendment to the bill, H.R. 6164.

The question was taken; and (two-thirds of those voting having responded in the affirmative) the rules were suspended and the Senate amendment was concurred in.

A motion to reconsider was laid on the table.

DIETARY SUPPLEMENT AND NONPRESCRIPTION DRUG CONSUMER PROTECTION ACT

Mr. BARTON of Texas. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 3546) to amend the Federal Food, Drug, and Cosmetic Act with respect to serious adverse event reporting for dietary supplements and nonprescription drugs, and for other purposes.

The Clerk read as follows:

S. 3546

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Dietary Supplement and Nonprescription Drug Consumer Protection Act''.

SEC. 2. SERIOUS ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

''Subchapter H—Serious Adverse Event Reports

''SEC. 760. SERIOUS ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS.

''(a) DEFINITIONS.—In this section:

''(1) ADVERSE EVENT.—The term 'adverse event' means any health-related event associated with the use of a nonprescription drug that is adverse, including—

''(A) an event occurring from an overdose of the drug, whether accidental or intentional;

''(B) an event occurring from abuse of the drug;

''(C) an event occurring from withdrawal from the drug; and

''(D) any failure of expected pharmacological action of the drug.

''(2) NONPRESCRIPTION DRUG.—The term 'nonprescription drug' means a drug that is—

''(A) not subject to section 503(b); and

''(B) not subject to approval in an application submitted under section 505.

''(3) SERIOUS ADVERSE EVENT.—The term 'serious adverse event' is an adverse event that—

''(A) results in—

''(i) death;

''(ii) a life-threatening experience;

''(iii) inpatient hospitalization;

''(iv) a persistent or significant disability or incapacity; or

''(v) a congenital anomaly or birth defect; or

''(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

''(4) SERIOUS ADVERSE EVENT REPORT.—The term 'serious adverse event report' means a report that is required to be submitted to the Secretary under subsection (b).

''(b) REPORTING REQUIREMENT.—

''(1) IN GENERAL.—The manufacturer, packer, or distributor whose name (pursuant to section 502(b)(1)) appears on the label of a nonprescription drug marketed in the United States (referred to in this section as the 'responsible person') shall submit to the Secretary any report received of a serious adverse event associated with such drug when used in the United States, accompanied by a copy of the label on or within the retail package of such drug.

''(2) RETAILER.—A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the nonprescription drug to submit the required reports for such drugs to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with such drug that are reported to the retailer through the address or telephone number described in section 502(x).

''(c) SUBMISSION OF REPORTS.—

''(1) TIMING OF REPORTS.—The responsible person shall submit to the Secretary a serious adverse event report no later than 15 business days after the report is received through the address or phone number described in section 502(x).

''(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, no later than 15 business days after the new information is received by the responsible person.

''(3) CONSOLIDATION OF REPORTS.—The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

''(4) EXEMPTION.—The Secretary, after providing notice and an opportunity for comment from interested parties, may establish an exemption to the requirements under paragraphs (1) and (2) if the Secretary determines that such exemption would have no adverse effect on public health.

''(d) CONTENTS OF REPORTS.—Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for nonprescription drugs, and may be accompanied by additional information.

''(e) MAINTENANCE AND INSPECTION OF RECORDS.—

''(1) MAINTENANCE.—The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

''(2) RECORDS INSPECTION.—

''(A) IN GENERAL.—The responsible person shall permit an authorized person to have access to records required to be maintained under this section, during an inspection pursuant to section 704.

''(B) AUTHORIZED PERSON.—For purposes of this paragraph, the term 'authorized person' means an officer or employee of the Department of Health and Human Services who has—

''(i) appropriate credentials, as determined by the Secretary; and

''(ii) been duly designated by the Secretary to have access to the records required under this section.

''(f) PROTECTED INFORMATION.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntarily submitted to the Secretary shall be considered to be—

''(1) a safety report under section 756 and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

''(2) a record about an individual under section 552a of title 5, United States Code (commonly referred to as the 'Privacy Act of 1974') and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the 'Freedom of Information Act'), and shall not be publicly disclosed unless all personally identifiable information is redacted.

''(g) RULE OF CONSTRUCTION.—The submission of any adverse event report in compliance with this section shall not be construed as an admission that the nonprescription drug involved caused or contributed to the adverse event.

''(h) PREEMPTION.—

''(1) IN GENERAL.—No State or local government shall establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for nonprescription drugs, that is different from, in addition to, or otherwise not identical to, this section.

''(2) EFFECT OF SECTION.—

''(A) IN GENERAL.—Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

''(B) PERSONALLY-IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

''(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

''(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

''(C) USE OF SAFETY REPORTS.—Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 756.

''(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.''.

(b) MODIFICATIONS.—The Secretary of Health and Human Services may modify requirements under the amendments made by this section in accordance with section 553 of title 5, United States Code, to maintain consistency with international harmonization efforts over time.

(c) PROHIBITED ACT.—Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amended by—

(1) striking '', or 704(a);'' and inserting '', 704(a), or 760;''; and

(2) striking '', or 564'' and inserting '', 564, or 760''.

(d) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(x) If it is a nonprescription drug (as defined in section 760) that is marketed in the United States, unless the label of such drug includes a domestic address or domestic phone number through which the responsible person (as described in section 760) may receive a report of a serious adverse event (as defined in section 760) with such drug.''.

(e) EFFECTIVE DATES.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section shall take effect 1 year after the date of enactment of this Act.

(2) MISBRANDING.—Section 502(x) of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall apply to any nonprescription drug (as defined in such section 502(x)) labeled on or after the date that is 1 year after the date of enactment of this Act.

(3) GUIDANCE.—Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance on the minimum data elements that should be included in a serious adverse event report described under the amendments made by this Act.

SEC. 3. SERIOUS ADVERSE EVENT REPORTING FOR DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

''SEC. 761. SERIOUS ADVERSE EVENT REPORTING FOR DIETARY SUPPLEMENTS.

''(a) DEFINITIONS.—In this section:

''(1) ADVERSE EVENT.—The term 'adverse event' means any health-related event associated with the use of a dietary supplement that is adverse.

''(2) SERIOUS ADVERSE EVENT.—The term 'serious adverse event' is an adverse event that—

''(A) results in—

''(i) death;

''(ii) a life-threatening experience;

''(iii) inpatient hospitalization;

''(iv) a persistent or significant disability or incapacity; or

''(v) a congenital anomaly or birth defect; or

''(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

''(3) SERIOUS ADVERSE EVENT REPORT.—The term 'serious adverse event report' means a report that is required to be submitted to the Secretary under subsection (b).

''(b) REPORTING REQUIREMENT.—

''(1) IN GENERAL.—The manufacturer, packer, or distributor of a dietary supplement whose name (pursuant to section 403(e)(1)) appears on the label of a dietary supplement marketed in the United States (referred to in this section as the 'responsible person') shall submit to the Secretary any report received of a serious adverse event associated with such dietary supplement when used in the United States, accompanied by a copy of the label on or within the retail packaging of such dietary supplement.

''(2) RETAILER.—A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the dietary supplement to submit the required reports for such dietary supplements to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with such dietary supplement that are reported to the retailer through the address or telephone number described in section 403(y).

''(c) SUBMISSION OF REPORTS.—

''(1) TIMING OF REPORTS.—The responsible person shall submit to the Secretary a serious adverse event report no later than 15 business days after the report is received through the address or phone number described in section 403(y).

''(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, no later than 15 business days after the new information is received by the responsible person.

''(3) CONSOLIDATION OF REPORTS.—The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

''(4) EXEMPTION.—The Secretary, after providing notice and an opportunity for comment from interested parties, may establish an exemption to the requirements under paragraphs (1) and (2) if the Secretary determines that such exemption would have no adverse effect on public health.

''(d) CONTENTS OF REPORTS.—Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for dietary supplements, and may be accompanied by additional information.

''(e) MAINTENANCE AND INSPECTION OF RECORDS.—

''(1) MAINTENANCE.—The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

''(2) RECORDS INSPECTION.—

''(A) IN GENERAL.—The responsible person shall permit an authorized person to have access to records required to be maintained under this section during an inspection pursuant to section 704.

''(B) AUTHORIZED PERSON.—For purposes of this paragraph, the term 'authorized person' means an officer or employee of the Department of Health and Human Services, who has—

''(i) appropriate credentials, as determined by the Secretary; and

''(ii) been duly designated by the Secretary to have access to the records required under this section.

''(f) PROTECTED INFORMATION.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntarily submitted to the Secretary shall be considered to be—

''(1) a safety report under section 756 and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

''(2) a record about an individual under section 552a of title 5, United States Code (commonly referred to as the 'Privacy Act of 1974') and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the 'Freedom of Information Act'), and shall not be publicly disclosed unless all personally identifiable information is redacted.

''(g) RULE OF CONSTRUCTION.—The submission of any adverse event report in compliance with this section shall not be construed as an admission that the dietary supplement involved caused or contributed to the adverse event.

''(h) PREEMPTION.—

''(1) IN GENERAL.—No State or local government shall establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for dietary supplements, that is different from, in addition to, or otherwise not identical to, this section.

''(2) EFFECT OF SECTION.—

''(A) IN GENERAL.—Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

''(B) PERSONALLY-IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

''(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

''(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

''(C) USE OF SAFETY REPORTS.—Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 756.

''(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.''.

(b) PROHIBITED ACT.—Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amended by—

(1) striking '', or 760;'' and inserting '', 760, or 761;''; and

(2) striking '', or 760'' and inserting '', 760, or 761''.

(c) MISBRANDING.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

''(y) If it is a dietary supplement that is marketed in the United States, unless the label of such dietary supplement includes a domestic address or domestic phone number through which the responsible person (as described in section 761) may receive a report of a serious adverse event with such dietary supplement.''.

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section shall take effect 1 year after the date of enactment of this Act.

(2) MISBRANDING.—Section 403(y) of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall apply to any dietary supplement labeled on or after the date that is 1 year after the date of enactment of this Act.

(3) GUIDANCE.—Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance on the minimum data elements that should be included in a serious adverse event report as described under the amendments made by this Act.

SEC. 4. PROHIBITION OF FALSIFICATION OF REPORTS.

(a) IN GENERAL.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 760 or 761) or the falsification of a serious adverse event report (as defined under section 760 or 761) submitted to the Secretary.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect 1 year after the date of enactment of this Act.

SEC. 5. IMPORTATION OF CERTAIN NONPRESCRIPTION DRUGS AND DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

(1) in subsection (a), by inserting after the third sentence the following: ''If such article is subject to a requirement under section 760 or 761 and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 760 or 761) has not complied with a requirement of such section 760 or 761 with respect to any such article, or has not allowed access to records described in such section 760 or 761, then such article shall be refused admission, except as provided in subsection (b) of this section.''; and

(2) in the second sentence of subsection (b)—

(A) by inserting ''(1)'' before ''an article included'';

(B) by inserting before ''final determination'' the following: ''or (2) with respect to an article included within the provision of the fourth sentence of subsection (a), the responsible person (as defined in section 760 or 761) can take action that would assure that the responsible person is in compliance with section 760 or 761, as the case may be,''; and

(C) by inserting '', or, with respect to clause (2), the responsible person,'' before ''to perform''.

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of enactment of this Act.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Texas (Mr. BARTON) and the gentleman from New Jersey (Mr. PALLONE) each will control 20 minutes.

The Chair recognizes the gentleman from Texas.

Mr. BARTON of Texas. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of Senate 3546, the Dietary Supplement and Nonprescription Drug Consumer Protection Act, and urge its adoption.

Mr. Speaker, I reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, could I ask for a copy of the legislation at this time? We seem to be concerned about the fact that changes have been made that we were not aware of on the Democratic side.

Mr. BARTON of Texas. Mr. Speaker, if the gentleman will yield, there are no changes on this bill that I am aware of.

The SPEAKER pro tempore. Could the gentleman provide the gentleman a copy of the bill?

Mr. BARTON of Texas. We will provide a copy, Mr. Speaker.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of S. 3546, the Dietary Supplement and Nonprescription Drug Consumer Protection Act. By some estimates, the dietary supplement industry is a $20 billion industry. Over half the American population regularly uses dietary supplements, with as many as 60 percent of Americans using dietary supplements daily in an effort to maintain or improve their healthy lifestyles.

Many responsible dietary supplement companies and manufacturers already voluntarily report serious adverse events associated with their products to the FDA. However, in order to ensure the safety of consumers, all companies should be required by law to report such events. This bill accomplishes that goal.

The legislation before us today would amend the Food, Drug, and Cosmetic Act to require that the manufacturer, packer or distributor of a dietary supplement or over-the-counter drug notify the FDA within 15 business days of any serious adverse event reports it receives that are associated with one of their dietary supplements or over-the-counter products.

A serious adverse event is described as a health-related event that results in death, a life-threatening experience, in-patient hospitalization, a persistent or significant disability or incapacity, or congenital anomaly or birth defect.

Adverse event reports provide an early warning signal to the FDA about potential product problems, like product contamination or adulteration, tampering, bioterrorism and ingredient safety issues. By requiring that this information be submitted to a single source, manufacturers increase the likelihood that problems will be identified more quickly and fewer consumers will be affected.

Although the FDA currently receives adverse event reports from consumers, health care providers, poison control centers and even many manufacturers on a voluntary basis, this legislation will ensure that a greater number of serious adverse event reports are transmitted to the FDA for review.

Consumers should be assured that when a serious incident happens, the manufacturer will be held responsible for informing the Federal agency that regulates these products. Adverse event reporting by the manufacturer is already required for other FDA regulated products, such as medical devices, prescription drugs and certain over-the-counter-drugs. It is time that we require the same reporting standards for dietary supplements, and this change will help protect consumers and build greater confidence in the safety of dietary supplements.

Again, I would like to thank Senators HATCH, HARKIN and DURBIN, as well as all the industry and consumer groups who worked hard on developing this legislation, and I urge my colleagues to join me in supporting it.

Mr. Speaker, I reserve the balance of my time.

Mr. BARTON of Texas. Mr. Speaker, I yield 2 minutes to the gentleman from Georgia (Mr. PRICE).

Mr. PRICE of Georgia. Mr. Speaker, I appreciate the chairman yielding me time.

Mr. Speaker, I rise in opposition to this bill. Having just seen this legislation within the last hour, this is a significant change to current law. It is one that has had no House hearings during this session. This is what we used to describe at the State level as the dangerous time for legislation, and this is clearly one of those instances.

I don't think that anybody is opposed to decreasing the number of adverse events or of serious adverse events. But when you read through the bill, the level of problem that can occur that would result in an adverse event can be relatively minor; an adverse event occurring from the abuse of a drug, which would require companies to report to the FDA, adverse event occurring from the withdrawal from a drug, any failure of expected pharmacologic action of the drug itself. This is just a huge reach right at this point for the FDA and the Secretary.

So I would encourage the House to not support this bill. I would encourage

the House to go through regular order on this piece of legislation, which is a significant change, and would ask for the House to turn down this suspension bill.

Mr. PALLONE. Mr. Speaker, I reserve my time.

Mr. BARTON of Texas. Mr. Speaker, I yield 2 minutes to the distinguished gentleman from Texas (Mr. SESSIONS).

Mr. SESSIONS. Mr. Speaker, I appreciate Chairman BARTON allowing me time to speak on this bill.

Mr. Speaker, I rise opposing this Dietary Supplemental and Nonprescription Drug Consumer Protection Act. The bill would replace the current system of adverse event reporting by medical professionals through the MedWatch Program with a mandatory system that would require manufacturers and retailers to keep records and to report to the FDA when they received reports of adverse events.

The bill redirects complaints of adverse effects away from local health responders, health care professionals, to manufacturers and retailers and then to the FDA. Consumers who are injured should be directed to medical professionals trained to determine whether the condition is caused by ingredients in the supplement or by other factors, not by self-diagnosis.

Secondly, this bill depends on those who may be responsible for types of drugs or drug supplements to report adverse effects to the FDA. Those guilty of violating the law are less likely to report adverse effects to the government and to follow the law.

I think this is a bad bill. I hope that we reject it.

Mr. PALLONE. Mr. Speaker, I yield back the balance of my time, and urge support of the bill.

Mr. BARTON of Texas. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, just in closing, I would urge support of the bill. The dietary supplement industry is a mature industry now, and I would estimate over 90 to 95 percent of those in the industry support passage of this bill. There are some segments of the industry that do oppose it.

This is a Senator ORRIN HATCH bill. I know that Congressman CANNON here in our body strongly supports it. I would hope that we would pass it.

Mr. CANNON. Mr. Speaker, I rise in support of S. 3546, the Dietary Supplement and Nonprescription Drug Consumer Protection Act. I am the sponsor of the companion bill, H.R. 6168, here in the House.

S. 3546 would require mandatory adverse event reporting of serious events for dietary supplements and over-the-counter drugs, OTCs, within the FDA.

Currently, an adverse event reporting system for supplements and some OTCs exists, yet it is strictly voluntary. Under the proposed system, manufacturers, packers or distributors of OTC drugs or dietary supplements in the United States must report to the FDA within 15 business days any serious adverse event associated with their products. Serious events include those that result in death, a life-threatening experience, inpatient hospitalization, disability or incapacity, birth defect, or medical/surgical intervention to prevent one of these outcomes.

S. 3546 brings needed regulation to guarantee consumer protection from non-legitimate companies. This legislation will expose corrupt businesses that are misleading consumers and breaking the law, as well as protecting individuals from serious health risks.

S. 3546 would not restrict nor limit access to dietary supplements but in fact would strengthen the regulatory structure for dietary supplements building greater consumer confidence in this category of FDA-regulated products.

Mandatory adverse event reporting would not affect the regulation of dietary supplements under DSHEA. Although manufacturers would be required to report serious adverse events to FDA, the Food Drug and Cosmetic Act clearly distinguishes dietary supplements from drugs.

S. 3546 would actually counter critics who believe dietary supplements are under-regulated and should be treated as drugs.

The dietary supplement industry is a $20 billion industry. It is estimated that over 60 percent of Americans regularly use dietary supplements to improve health. Consumers should be confident that these dietary supplements are legitimate.

S. 3546 is supported by the major consumer and trade associations. Including the Consumer's Union, the Center for Science in the Public Interest, the Consumer Healthcare Products Association, the National Nutritional Foods Association, the Council for Responsible Nutrition, the American Herbal Products Association, and the United Natural Products Alliance.

The Dietary Supplement and Nonprescription Drug Consumer Act is necessary legislation to safeguard Americans and uncover illegal manufacturers who are jeopardizing consumer's health.

Mr. BARTON of Texas. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Texas (Mr. BARTON) that the House suspend the rules and pass the Senate bill, S. 3546.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds of those voting have not responded in the affirmative.

Mr. BARTON of Texas. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the Chair's prior announcement, further proceedings on this question will be postponed.

PREMATURITY RESEARCH EXPANSION AND EDUCATION FOR MOTHERS WHO DELIVER INFANTS EARLY ACT

Mr. BARTON of Texas. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 707) to reduce preterm labor and delivery and the risk of pregnancy-related deaths and complications due to pregnancy, and to reduce infant mortality caused by prematurity, as amended.

The Clerk read as follows:

S. 707

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act'' or the ''PREEMIE Act''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.
TITLE I—REDUCING PRETERM LABOR AND DELIVERY AND THE RISK OF PREGNANCY-RELATED DEATHS AND COMPLICATIONS
Sec. 101. Purpose.
Sec. 102. Research relating to preterm labor and delivery and the care, treatment, and outcomes of preterm and low birthweight infants.
Sec. 103. Public and health care provider education and support services.
Sec. 104. Interagency Coordinating Council on Prematurity and Low Birthweight.
Sec. 105. Surgeon general's conference on preterm birth.
TITLE II—CONTACT LENS CONSUMER PROTECTION
Sec. 201. Short title.
Sec. 202. Availability of contact lenses.
Sec. 203. Prescriber verification.
Sec. 204. FTC Studies.
Sec. 205. FDA consumer safety study.
TITLE III—MISCELLANEOUS PROVISIONS
Sec. 301. Effective date of certain Head Start regulations.
Sec. 302. Medicare Critical Access Hospital Designation.

TITLE I—REDUCING PRETERM LABOR AND DELIVERY AND THE RISK OF PREGNANCY-RELATED DEATHS AND COMPLICATIONS

SEC. 101. PURPOSE.

It the purpose of this title to—

(1) reduce rates of preterm labor and delivery;

(2) work toward an evidence-based standard of care for pregnant women at risk of preterm labor or other serious complications, and for infants born preterm and at a low birthweight; and

(3) reduce infant mortality and disabilities caused by prematurity.

SEC. 102. RESEARCH RELATING TO PRETERM LABOR AND DELIVERY AND THE CARE, TREATMENT, AND OUTCOMES OF PRETERM AND LOW BIRTHWEIGHT INFANTS.

(a) GENERAL EXPANSION OF CDC RESEARCH.—Section 301 of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

''(e) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand, intensify, and coordinate the activities of the Centers for Disease Control and Prevention with respect to preterm labor and delivery and infant mortality.''.

(b) STUDIES ON RELATIONSHIP BETWEEN PREMATURITY AND BIRTH DEFECTS.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall, subject to the availability of appropriations, conduct ongoing epidemiological studies on the relationship between